UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	)	**Criminal No.: 09-CR-10330-GAO**
v.	)	
STRYKER BIOTECH, LLC,	)	
MARK PHILIP,	)	
WILLIAM HEPPNER,	)	
DAVID ARD and	)	
JEFFREY WHITAKER,	)	
Defendants.	)	

GOVERNMENT'S MOTION TO EXCLUDE EXPERT TESTIMONY OF JONATHAN GRAUER AND WILLIAM CATON III

Introduction and Summary of Argument

The government respectfully moves to exclude expert testimony of two surgeons identified as experts by the defendants, Jonathan Grauer and William Caton III. As set forth in their Disclosures of Anticipated Expert Testimony (attached hereto as Exhibits A and B), each is seeking to testify impermissibly as an expert in two different ways: (1) offering factual testimony about purely personal experiences and observations, such as his use of OP-1 and Calstrux and interactions with Stryker sales representatives, but doing so as an "expert" so as to suggest that such personal experiences and observations have a broader application; (2) offering expert testimony about the physical properties of a combination of Calstrux and OP-1, without having

done any studies, clinical or otherwise, on that topic.[1] As to the factual testimony that defendants seek to dress up as expert testimony, the government seeks their exclusion as experts. As to the purportedly expert testimony that is not based on appropriate science, the government seeks exclusion, or, in the alternative, a Daubert hearing.

Background

On October 29, 2009, a grand jury returned an Indictment against Stryker Biotech, Mark Philip (Stryker Biotech's former President), William Heppner (Stryker Biotech's National Sales Director), David Ard (Stryker Biotech's Western Regional Manager), and Jeffrey Whitaker (Stryker Biotech's Southeastern Regional Manager). The case is scheduled for trial on November 7, 2011, and involves various charged crimes largely arising from the promotion of a mixture of two products that were not FDA approved as a combined or mixed product.

As charged in the Indictment, Stryker obtained a Humanitarian Device Exemption ("HDE") from the FDA for medical devices known as OP-1. OP-1 was a bone morphogenic

[1]In contrast, the government's expert disclosures identified, as a prophylactic measure, a number of surgeons who are percipient witnesses in that they are expected to testify as to the facts of their interactions with Stryker Biotech sales representatives and their personal experiences using and observing Stryker Biotech products. As set forth in the government's expert disclosure (attached hereto as Exhibit C):

> The government's list of potential experts, attached hereto as Exhibit A, consists of witnesses whose primary testimony will be factual observations and impressions made: (1) during and after interacting with Stryker Biotech and its employees/agents; and (2) while providing care and treatment to certain patients involving one or more of Stryker Biotech's medical devices (OP-1 Implant, OP-1 Putty and Calstrux). . . . The government submits that this is not expert testimony governed by Fed. R. Evid. 702. However, if the Court determines that some aspect of this testimony is governed by Fed. R. Evid. 702, out of an abundance of caution the government is making this disclosure.

protein and had the ability to stimulate, repair and regenerate bone. There were specific surgeries (for long bone and spine) that had been clinically studied by Stryker, submitted to the FDA and which formed the basis for the HDE. In the early years that OP-1 was on the market (2002-2004), Stryker "received feedback from surgeons that OP-1 handled poorly (like wet sand) and did not provide enough product volume." Indictment ¶21. In response to these complaints, Stryker developed Calstrux, a product with a malleable, "silly-putty" type of consistency that Stryker intended to be mixed with OP-1 as a "carrier" or "extender" to increase the volume and improve the handling qualities of OP-1. Id. ¶22. However, Stryker did not advise the FDA that it intended to use Calstrux as a mixing agent for OP-1, instead representing that it would be used as a bone void filler. Id. ¶23. Stryker never applied to the FDA for approval of a mixture of OP-1 and Calstrux, nor did the FDA ever approve any such mixed device or use. Id. ¶25. Each of the defendants promoted or caused to be promoted to surgeons and surgical staff a combination of Calstrux and OP-1. E.g., Indictment ¶32.

In late 2005 and early 2006, the defendants learned of adverse event reports in patients who had surgical implantation of a mixture of OP-1 and Calstrux. Adverse events from this mixture included migration of the mixture from the surgical site, which led to the need for reoperation to flush the mixture which had migrated from the surgical site and looked like "oatmeal" or "grits." Indictment ¶33. The defendants learned in this time period that Stryker Biotech was considering sending a "dear doctor" letter to surgeons advising them of these adverse events associated with a mixture of OP-1 and Calstrux. E.g., Indictment ¶¶34, 36. In correspondence involving defendants Heppner, Whitaker and Ard, there was discussion that such

a letter would harm sales of OP-1, in part because "many surgeons are just handed the product prior to implantation and think its all OP-1." Indictment ¶37.

In addition to knowing that many surgeons had been misled by the promotion of a mixture of Calstrux and OP-1, the individual sales manager defendants (Heppner, Ard and Whitaker) were all specifically trained on March 1, 2006 that the consequences of promoting a mixture of OP-1 and Calstrux included that each could be criminally prosecuted for "Criminal misbranding", which was "illegal" and a "Serious offence. . ." Indictment ¶38. The Indictment further alleges that despite knowing that the promotion of a mixture of OP-1 and Calstrux was illegal, all the individual defendants continued to do so. Id. ¶40.

Thus, important factual issues in the trial will include the nature of the interaction (specifically the promotion) between the Stryker sales representatives and the surgeons and surgical staff, including representations about OP-1, Calstrux or the mixture. By seeking to introduce "expert" testimony about these interactions, the defendants are inappropriately attempting to amplify and extrapolate that testimony beyond the mere factual testimony which it is.

Another important factual issue in the trial, as noted above, is that Stryker never conducted any clinical trial of a mixture of OP-1 and Calstrux. Yet, Stryker and its co-defendants appear to be trying to ameliorate that failure by having their experts testify that they did not expect the combination of OP-1 and Calstrux to "result in a biologically unique 'third product.'" Exhibit A at p. 3. However, neither of their experts have performed any scientific studies that would justify, as matter of evidence, such expert testimony.

Argument

Expert testimony is governed by Federal Rule of Evidence 702, which provides:

> If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

As set forth in more detail below, by straight application of this rule, a surgeon should not be able to offer expert testimony on the nature of sales representative/surgeon interactions because, among other things, the testimony is based only on his personal experience and not "sufficient facts or data."

The proffered expert testimony on the properties of the combination of Calstrux and OP-1 does not meet the standards enunciated in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). "[U]nder the [Federal] Rules [of Evidence] the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." Daubert, 509 U.S. at 589. Rule 702 is "premised on an assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline." Id. at 592.

A. Defendants' proposed experts should be prohibited from offering factual testimony under the guise of expert testimony.

Dr. Grauer apparently intends to testify about: the medical reasons he uses BMPs, the manner in which he performs posterior lumbar fusions, the role that medical device sales representatives play in the surgeries he performs, and his relationship and interaction with his medical device representatives (apparently including those from Stryker). Ex. A, *passim*. None

of these areas involves any expertise; rather, it is an effort by the defendants to improperly extrapolate beyond his personal experiences under the veneer of expert testimony. For example, Dr. Grauer has no particular "expertise" in the physician/sales representative relationship. Based on his expert disclosure he apparently has a view on the contours of that relationship, and if he wants to testify as to the manner in which he personally interacts with his Stryker sales representatives he should do so as a fact witness, not as an expert witness trying to impart to the jury that his unique experiences are entitled to any more weight than the experiences of any other physician. Expert witnesses may not usurp exclusive function of jury to weigh evidence and to determine credibility, "[n]or may expertness be the medium for injecting into the record material and information not a part of the expert's qualifications and otherwise inadmissible through his lips." U.S. v. Ward, 169 F.2d 460 (3rd Cir. 1948).

Similarly, Dr. Caton apparently intends to testify about the reasons he uses BMPs and "prefers their use over iliac crest in certain PLF surgeries[,]" his understanding "that OP-1 and Calstrux were two separate products," his understanding that such "combination may be 'off-label,' [but] he determined that such use was in the best interest of his patients," "that he bases his surgical decisions (including decisions to proceed in a non-FDA-approved, or 'off-label,' manner) on his own medical research into the products at issue," that his use of a mixture of Calstrux and OP-1 "routinely resulted in successful outcomes," and his interaction with medical device sales representatives (apparently including those from Stryker). Ex. B at 2-5. Again, these are areas in which Dr. Caton has personal experiences and personal views, but no particular expertise. For example, if Dr. Caton was aware that OP-1 and Calstrux were two

separate products is not an appropriate subject of expert testimony; it is instead an inappropriate attempt to inject the aura of expertise into an important factual issue in this trial.

B. The "scientific" aspects of the proffered testimony of Drs. Grauer and Caton do not meet the Daubert standard an should be excluded.

Dr. Grauer expects to testify "that the combination of a BMP [OP-1] and a BVF [Calstrux] typically is not expected to alter the action of the BMP [OP-1] or otherwise result in a biologically unique 'third product.'" Ex. A at 3. However, he provides no scientific basis for this conclusion, such as clinical trials or other tests of the properties of a combination of Calstrux and OP-1.

Dr. Grauer also expects to testify that "none of the incidences of possibly OP-1-related heterotopic bone growth of which he was aware was of lasting clinical concern." Id. at 4. Again, he provides no basis for this opinion, such as identifying the incidences of OP-1-related heterotopic bone growth, providing the medical records of those patients and the subsequent history of those patients so as to conclude that their heterotopic bone growth was (or was not) a matter of "lasting clinical concern."

"Dr. Caton is expected to testify that mixing OP-1 and Calstrux . . . neither alters the inherent properties of OP-1 nor leads to higher rates of infection and/or so-called 'adverse events.'" Ex. B at 3-4. However, he provides no basis for this opinion, such as clinical trials or other tests of the properties of a combination of Calstrux and OP-1. The government is not aware of any such clinical trial that has ever been performed by Dr. Caton or anyone else.

"Dr. Caton is further expected to testify that he has not observed any adverse events in any of the spinal fusion patients in whom he implanted OP-1, based upon the approximately 100

surgeries he performed with that product, in the majority of which Dr. Caton used a mixture of OP-1 combined with Calstrux. Dr. Caton's opinions are also based on his average post-surgical infection rate of less than 1% in these procedures, which rate was the same for patients receiving either OP-1 alone or OP-1 mixed with Calstrux; his personal observation of his patients in the course of post-surgical care and treatment. . ." Id. at 4. Yet, the basis for such testimony has not been provided. Dr. Caton, despite requests to Stryker's counsel, has not provided any information about "the approximately 100 surgeries" – no identification of the patients, no production of their medical records, no identification of which surgeries used just OP-1, of which surgeries used a mixture of OP-1 and Calstrux, no identification of which mixture recipes he used for which patients, no identification of which patients did have adverse events, no identification of the types of adverse events, and no data showing whether his adverse event rate was the same in patients who received only OP-1 versus patients who received the mixture.

Under Daubert, the factors that determine the admissibility of expert testimony include: (1) whether the theory or technique been tested; (2) whether the theory or technique been subjected to peer review and publication; (3) what the known or potential rate of error for the particular scientific technique is; and (4) whether the scientific technique has been generally accepted in the scientific community. 509 U.S. at 592-594. None of the "scientific" opinions proffered by Dr. Grauer or Dr. Caton meets any of these criteria.

For example, as to their opinion that the mixture of OP-1 and Calstrux does not lead to a "third product" or alter the properties of OP-1, defendants' experts refer to no testing of that theory, let alone one that has been subjected to peer review and publication. As to their opinions

about the adverse events from a combination of OP-1 and Calstrux, they again cite no testing, and only generally aver to their own anecdotal experience. However, relying on "underlying data that was purely anecdotal and without scientific basis" is inappropriate. United States v. Giambro, 544 F.3d 26, 33 (1st Cir. 2008). Moreover, when an expert testifies to scientific knowledge, to satisfy the reliability element of Daubert analysis for admission of expert testimony, the expert's opinions, "must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation; the expert must have good grounds for his or her belief." Montgomery v. Mitsubishi Motors Corp., 448 F.Supp.2d 619 (E.D. Pa. 2008)(internal quotations and citations omitted).

While the expert testimony inquiry is flexible, its "overarching subject is the scientific validity and thus the evidentiary relevance and reliability – of the principles that underlie a proposed submission." Daubert at 594-595. The "scientific" testimony proffered by Dr. Grauer and Caton does not meet even this flexible, yet meaningful, gate-keeping standard.

For all the foregoing reasons, the United States respectfully requests that the Court allow this motion.

Respectfully submitted,

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Date: September 9, 2011

I hereby certify that my colleague Susan G. Winkler contacted defendants' counsel of record by e-mail on September 7, 2011 to ask their position on this motion, and asked that they respond by close of business on September 8. Counsel for defendants Ard and Whitaker responded that they oppose. Counsel for defendants Stryker Biotech, Philip, and Heppner have not stated their position.

/s/ Gregory F. Noonan
Gregory F. Noonan
Assistant U.S. Attorney

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF)

/s/Gregory F. Noonan
Gregory F. Noonan
Assistant United States Attorney

Date: September 9, 2011